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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,766	06/20/2002	Martinas Kuslys	112843-043	2286
29157	7590	10/05/2004	EXAMINER	
BELL, BOYD & LLOYD LLC P. O. BOX 1135 CHICAGO, IL 60690-1135			SHAHNAN SHAH, KHATOL S	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/088,766

Applicant(s)

KUSLYS ET AL.

Examiner

Khatol S Shahnan-Shah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/20/2002</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' preliminary amendments of 6/20/2002 is acknowledged. Claims 1, 3-10 and 12 have been amended. Claim 11 has been canceled without prejudice. New claims 13-20 have been added. Specification pages 3, 8 and 9 have been amended. The title of the invention has been amended.
2. Claims 1-10 and 12-20 are pending and under consideration.

Information Disclosure Statement

3. Applicants' information disclosure statement of 3/20/2002 is acknowledged. The examiner has considered the references. See attached form 1449s.

Priority

4. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification. Priority statement is missing from the specification. A statement reading "This is a 371 of Application No. PCT/EP00/08910, filed 09/12/2000 which claims priority to British application No. 9923048.4 filed 09/29/1999." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of all nonprovisional parent applications referenced should be included.

Specification

5. The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains abbreviations MPa and SNF. Full name and description of these abbreviations are required when they appear first time in the specification. Appropriate correction is required.

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The use of the trademarks such as NOVOZYME and IMAC HP have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Appropriate correction is required.

Abstract

6. Applicants have submitted an abstract of disclosure from the parent case. Since the abstract of the disclosure does not commence on a separate sheet, it is recommended that a new abstract of the disclosure should be presented on a separate sheet, apart from any other text.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-10 and 12-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-35 of U.S. Patent No. 6777391. Although the conflicting claims are not identical, they are not patentably distinct from each other because

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claims of both applications are drawn to an infant formula comprising of whey protein, casein protein and free amino acids, method of making of said composition and a method of treating mal nutrition.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 1-10 and 12-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "tryptophan rich" in claims 1, 10, 12, 13 and 20 is a relative term, which renders the claims indefinite. The term " tryptophan rich " is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "about" in claims 2, 3, 7, 8, 9, 14, 15, and 17-19 is a relative term, which renders the claims indefinite. The term "about" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "substantially " in claim 6 is a relative term, which renders the claim indefinite. The term " substantially " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

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It is not clear what constitute the metes and bounds of “an effective amount” in claim 20.

Claims 4 and 16 are indefinite wherein the claims provide limitations “comprises a lipid source, a carbohydrate source and a protein source” It is unclear if applicants intend to add compounds which are sources for making lipids, carbohydrates and proteins, or they intent to add lipids and carbohydrates and proteins.

Claim 5 is indefinite as being dependent from indefinite claim 1.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1-10 and 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over XP -002158762 (prior art of record).

The claims are drawn to a composition (i.e. infant formula), method of producing and method of using of said formula for providing nutrition and treating malnutrition. The formula comprises whey protein, casein protein and free amino acids.

XP -002158762 teach a composition (i.e. infant formula) comprising whey protein, casein protein and free amino acids such as tryptophan, histidine and arginine (see abstract). XP -002158762 teach that the formula can be easily digested and utilized for nutritive compensation (i.e. method of treating malnutrition and providing nutrition to an infant). XP -002158762 teach method of making of said formula. XP -002158762 teach carbohydrate and lipid sources. XP -

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002158762 teach different concentration of these ingredients. Limitations such as different concentration are being viewed as limitations of optimizing experimental parameters.

It would have been prima facie obvious to one of ordinary skill in the art adjust the concentration of the composition taught by XP -002158762 to obtain the claimed composition.

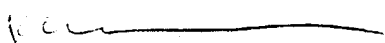
Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnian-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

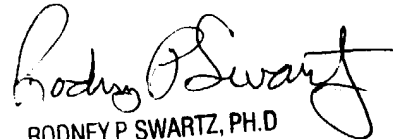
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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September 30, 2004


RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER